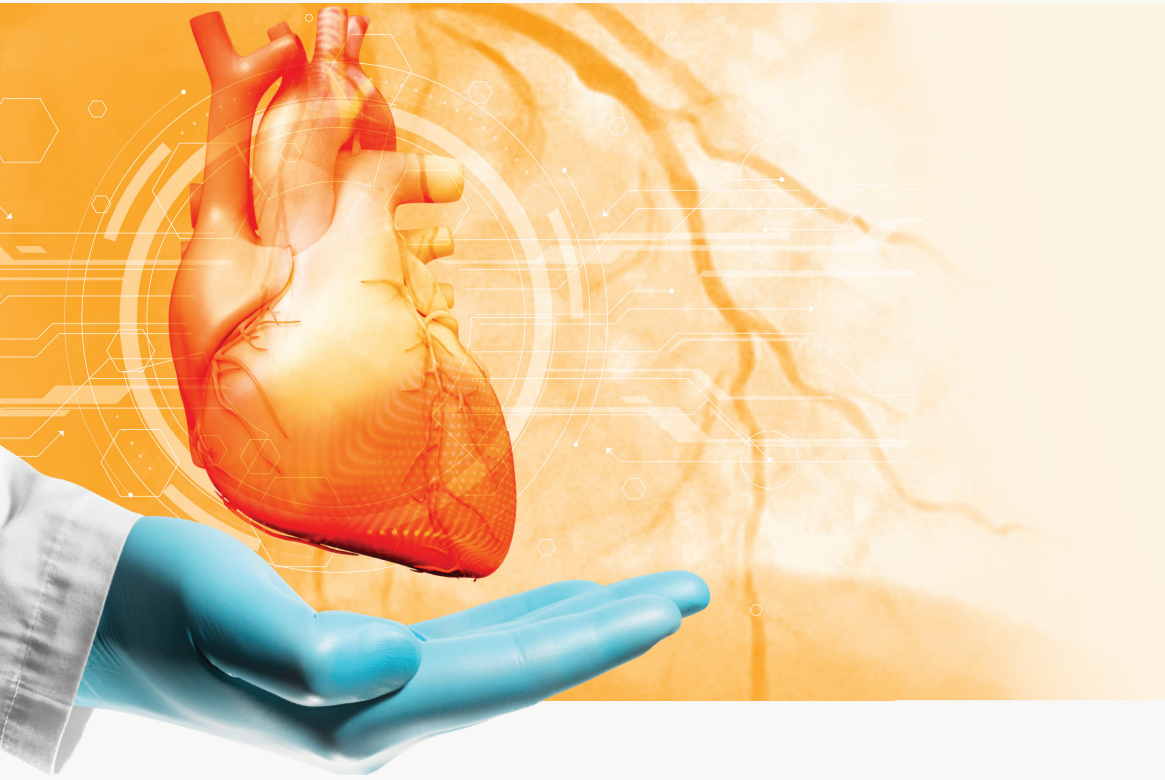
iVAC 2L - pVAD

Percutaneous Ventricular Assist Device

Natural pulsatile support for protected High-Risk PCI



General Context

Today, Percutaneous Mechanical Circulatory Support (MCS) can be used to facilitate High-risk Percutaneous Coronary Interventions (HR-PCIs).
The in-hospital mortality rate of high-risk PCI patients is higher than usual, and may reach up to 28% after 30 days. Against this, the increasing use of prophylactic MCS in this setting aims to provide a backup to the circulatory system from the very first minutes of the intervention. This may reduce the risk of hemodynamic instability or circulatory collapse during manipulation of the coronary arteries and provide sufficient time to achieve optimal and complete revascularization[1],

The main goals of Left Ventricular (LV) short-term MCS include:

- ✓ LV unloading
- ✓ Reduction in Myocardial Oxygen Consumption (MVO_2)
- ✓ Reduction in LV afterload
- ✓ Optimization of coronary flow and end-organ perfusion

Purpose of protected High-Risk PCI with pVAD

With prophylactic MCS in HR-PCI, operators can expect a reduction in major adverse events.

Body of Evidence

The efficacy of MCS has been suggested by multiple comparative studies:

- The Protect II trial is the largest randomized controlled trial comparing MCS with IABP in high-risk percutaneous coronary interventions. The results show a significant reduction in Major Adverse Events after 90 days in the MCS group compared to the IABP group[1].
- An analysis of 198 high-risk patients undergoing mechanically assisted HR-PCI at the Erasmus Medical Center (Rotterdam, NL) showed that MCS improved survival and reduced adverse events when compared with standard-of-care only[2].
- The PULSE trial shows LV unloading, increased mean arterial pressure (MAP) and lower myocardial oxygen consumption (MVO_2) with the use of iVAC 2L in high-risk PCI[3, 4].
- A recently published expert consensus recommends that MCS may be considered in highly selected patients undergoing HR-PCI in case of acceptable femoral access (> 6 mm in diameter of the common femoral artery with no severe tortuosity) and should be preferred instead of IABP and VA-ECMO[5].

iVAC 2L overview

iVAC 2L is a short term, fully percutaneous, 17Fr transfemoral LVAD that effectively generates blood flow up to 2 L/min. By actively unloading the LV, the iVAC 2L provides critical haemodynamic support during high-risk revascularization procedures, in cases of acute myocardial infarction and in cardiogenic shock. [4, 6-8]

What is the labeled indication for the iVAC 2L system?

iVAC 2L is intended for use in patients with impaired LV function which require LV MCS for up to 24 hours. This includes LV support in the following situations:

- Elective or emergent HR-PCIs for Coronary Heart Disease
- Cardiogenic shock of various etiologies
- Acute Decompensated Heart failure
- High-risk electrophysiological procedures

Mechanism of action

The operating mechanism of the iVAC 2L is a patented 2-way valve integrated in a 17Fr single lumen and bi-directional, 1000 mm long catheter. This catheter is connected to an extracorporeal membrane pump. The system is compatible with a standard IABP console and does not require dedicated hardware. When the heart is in the **systolic** phase, blood is aspirated from the ventricle through the tip of the catheter and transported via the lumen into the membrane pump. During the **diastolic** phase, the membrane pump (with the IABP console as a driver) directs the blood back through the catheter to the ascending aorta by opening the 2-way valve.The pulsatile synchronization between closing of the aortic valve and the opening of the catheter valve ensures that the aortic valve function is not impaired, but supported.

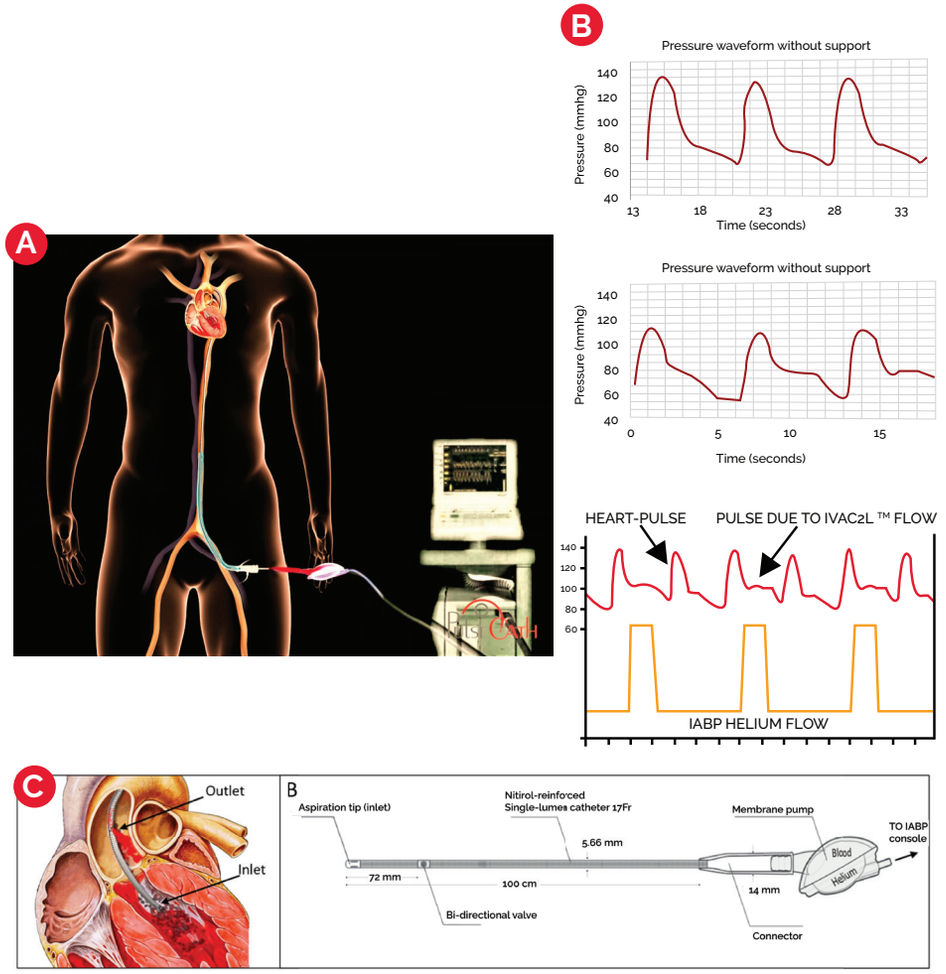


Figure 5. *(A) Implantation of iVAC 2L. The catheter is introduced through the common femoral artery and positioned with the tip inside the LV. The catheter is connected to a membrane pump which is in turn connected to a conventional IABP console. (B) Effect of iVAC 2L on the aortic pressure waveform showing diastolic augmentation and additional pulsatility in the diastolic descent. (C) Schematic view of iVAC 2L showing its main working components. Effective length of catheter as indicated by the arrows is 920 mm.*

General features:

- Trans-aortic short-term LV Assist Device
- Percutaneous insertion
- Actively ejects left ventricular blood into the ascending aorta
- 1.0 to 1.5 L/min (max. observed 2.0 L/min)[6] output to support the native heart
- Counter-pulsation system that creates additional pulsatility during diastole
- Driven by a conventional IABP console
- Non-significant hemolysis, fHb <10 µmol/L

Advantages

- ✓ Natural pulsatile support
- ✓ Fast and easy implementation
- ✓ Fully percutaneous approach
- ✓ Highly flexible catheter
- ✓ Cost effectiveness: iVAC 2L has an universally adaptable design that fully integrates with a standard IABP console

In addition, PulseCath iVAC 2L pumps using Pulsatile flow

There is a difference between pulsatile and continuous flow. Continuous flow reduces the motility of the aortic valve and may increase the aortic impedance. Furthermore, it has been related to worse end-organ perfusion. In contrast, synchronized flow as found in the iVAC 2L system creates additional pulsatility in the systemic vasculature, potentially improving peripheral perfusion. iVAC 2L may also optimize coronary blood flow thus increasing oxygen delivery to the myocardium while sparing it from the additional burden of pumping blood against increased aortic impedance[4].

References

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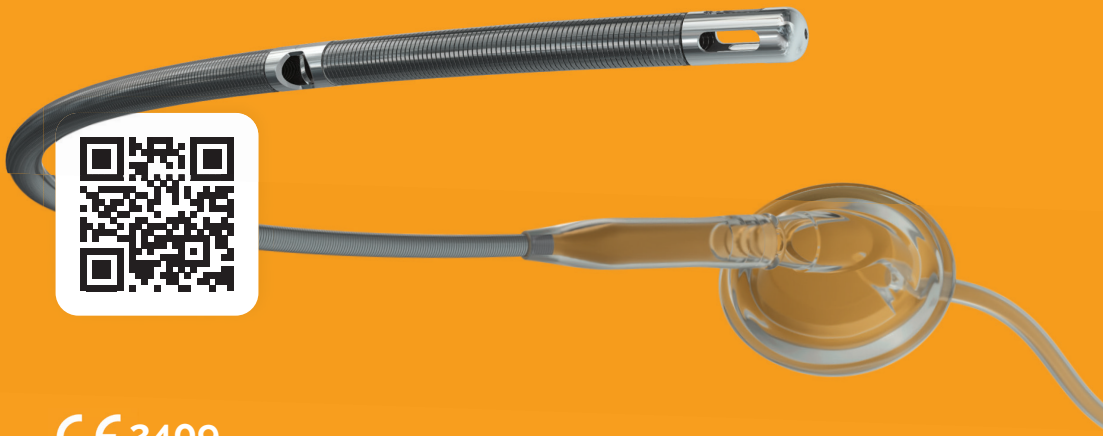
Ordering information

iVAC 2L®

Catalog number: LV17

Initial kit package contents:

- 1x LV17 catheter with insertion set
- 1x Membrane Pump
- 1x Catheter Protector
- 1x Extra PTFE Catheter Inner Tube
- Additional accessories kit: 18Fr introducer sheath, 16cm metal clamp, 50cc syringe



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